# PHARMACEUTICAL CARE IN THE MANAGEMENT OF PEOPLE WITH TYPE 2 DIABETES MELLITUS:

# A RANDOMIZED CONTROLLED TRIAL

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# PHARMACEUTICAL CARE IN THE MANAGEMENT OF PEOPLE WITH TYPE 2 DIABETES MELLITUS:

# A RANDOMIZED CONTROLLED TRIAL

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**DISSERTATION SUBMITTED IN FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTER OF MEDICAL SCIENCE**

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**Abstract**

Diabetes mellitus is a lifelong chronic condition that requires continuous healthcare and patient's self-management. Lifestyle modifications and adherence to anti-diabetes medications are the major determinants of therapeutic success in the management of diabetes. The fundamental goal of pharmacy practice today is to provide PC which directly influences effective, rational and safe medication use, leading to better health outcomes. Studies which evaluated the effects of PC in the management of people with diabetes found a statistically significant reduction in $HbA_{1C}$ in the intervention group. However, most studies in the literature were conducted in developed countries. Therefore, the present study is warranted to investigate the effects of a pharmaceutical care (PC) model in the management of people with type 2 diabetes in Malaysia.

A total of 241 people with type 2 diabetes were recruited from the Diabetes Clinic of the University Malaya Medical Centre (UMMC) and allocated at random to the control (n=121) or intervention (n=120) group. Participants in the intervention group received pharmaceutical care (PC) from an experienced pharmacist while those in the control group were provided the standard pharmacy service.

A range of clinical outcomes that included fasting blood glucose (FBG), glyclated haemoglobin ($HbA_{1C}$), lipid profile and blood pressure (BP); and non-clinical outcomes (medication adherence, knowledge of participants, quality of life and pharmaceutical care issues) were collected and analysed at baseline and then at 4, 8 and 12 months after the initiation of intervention.

At baseline, there was no significant difference in demographic and clinical characteristics of the participants between the control and intervention groups. Significant reductions in mean (standard deviation, SD) of FBG [9.4 (3.4) mmol/L versus 7.5 (2.3)

mmol/L, $HbA_{1C}$ [9.6 (1.3)% versus 8.2 (1.3)%], systolic BP [142.9 (18.4) mmHg versus 134.0 (15.1) mmHg], diastolic BP [79.5 (10.9) mmHg versus 77.0 (9.8) mmHg] were found between the control and intervention group 12 months after the provision of PC. In addition, medication adherence ($p = 0.001$) and knowledge of participants ($p < 0.001$) in the intervention group increased significantly. The control group on the other hand, showed no significant improvement in clinical outcomes.

During the study period, the pharmacist identified 408 PC issues (PCIs) and facilitated 598 PC interventions. Of these 408 PCIs, the pharmacist in this study managed to solve 333 (81.6%). Each drug -elated problem (DRP) were linked to at least three root causes that were related and directed to the participants (45.7%) or their caregivers (54.8%).

In conclusion, the provision of the PC model used in this study for the management of type 2 diabetes mellitus (T2DM) has produced positive effects on both clinical and behavioural outcomes of the intervention participants. Therefore, collaborative efforts between pharmacist and other healthcare professionals should be implemented in all healthcare institutions to achieve more effective, rational and safe medication use and hence, better clinical outcomes.

**Abstrak**

Diabetes mellitus adalah penyakit kronik yang memerlukan penjagaan kesihatan dan pengurusan yang berterusan sepanjang hayat oleh pesakit sendiri. Pengubahsuaian gaya hidup dan pematuhan kepada ubat-ubatan anti-diabetes adalah penentu utama untuk kejayaan terapeutik dalam pengurusan diabetes. Matlamat asas amalan farmasi pada zaman sekarang adalah untuk memberi penjagaan farmaseutikal (PC). Dengan secara langsung, PC yang diberikan akan mempengaruhi keberkesanaan, rasional dan pengunaan ubat-ubatan dengan selamat yang membawa hasil kesihatan yang lebih baik. Namun, kebanyakaan hasil kajian dalam kesusteraan hanya dijalankan di negara-negara yang maju. Oleh yang demikian, kajian tersebut diperlukan untuk menyiasat kesan sesuatu model PC dalam pengurusan orang yang menghidapi diabetes jenis 2 di Malaysia.diabetes.

Seramai 241 orang dengan diabetes jenis 2 dipilih dari Klinik Diabetes di Pusat Perubatan Universiti Malaya (PPUM) dan dibahagikan secara rawak ke dalam kumpulan kawalan (n = 121) dan intervensi (n = 120). Peserta-peserta dalam kumpulan intervensi menerima PC daripada seorang ahli farmasi yang berpengalaman, manakala peserta-peserta dalam kumpulan kawalan menerima perkhidmatan farmasi yang biasa.

Pelbagai hasil kajian klinikal termasuk paras glukosa darah semasa puasa (FBG), hemoglobin gliklat ($HbA_{1C}$), profil kolesterol dan tekanan darah (BP); dan hasil kajian bukan klinikal seperti pematuhan ubat, pengetahuan, kualiti hidup dan isu-isu penjagaan farmaseutikal, telah dikumpul dan dianalisis pada permulaan kajian serta pada bulan ke-4, ke-8 dan ke-12 selepas intervensi dimulakan.

Pada permulaan kajian, tidak terdapat sebarang perbezaan yang signifikan dari segi demografi dan ciri-ciri peserta di antara kumpulan kawalan dan intervensi. Namun, terdapat pengurangan yang signifikan ($p < 0.05$) ke atas ukuran purata (deviasi piawai, SD) di antara bacaan permulaan berbanding dengan bacaan akhir pengajian untuk FBG [9.4 (3.4) mmol/L berbanding 7.5 (2.3) mmol/L, $HbA_{1C}$ [9.6 (1.3)% berbanding 8.2 (1.3)%], BP sistolik [142.9 (18.4) mmHg berbanding 134.0 (15.1) mmHg], BP diastolik [79.5 (10.9) mmHg berbandimg 77.0 (9.8) mmHg] sertapeningkatan yang ketara dalam markah pematuhan kepada ubat-ubatan ($p = 0.001$) dan skor purata pengetahuan peserta mengenai diabetes ($p < 0.001$) diperhatikan dalam kumpulan intervensi. Manakala, kumpulan kawalan tidak menunjukkan sebarang pembaikan dalam hasil klinikalnya.

Dalam tempoh kajian tersebut, ahli farmasi berjaya mengenalpasti 408 isu-isu PC (PCIs) dan mencadangkan sebanyak 598 intervensi PC. Daripada jumlah 408 PCIs ini, ahli farmasi berjaya menyelesaikan 333 (81.6%) isu-isu PC. Setiap masalah yang berkaitan dengan ubat-ubatan (DRP) telah dikaitkan dengan sekurang-kurangnya tiga punca penyebab yang berkenalan dan ditujukan kepada peserta (45.7%) atau penjaga mereka (54.8%).

Kesimpulannya , pemberian sesuatu model PC dalam kajian tersebut untuk pengurusan diabetes mellitus jenis 2 di Malaysia menghasilkan kesan klinikal dan perubahan kelakuan secara positif pada peserta-peserta intervensi. Oleh itu, kerjasama di antara ahli-ahli farmasi dan profesional kesihatan yang lain perlu dilaksanakan di semua institusi kesihatan untuk mencapai hasil klinikal yang lebih berkesan, rasional dan penggunaan ubat-ubatan yang lebih selamat.

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| | |
|---|---|
| $\chi^2$ | Pearson chi-square |
| ACCORD | Action to Control Cardiovascular Risk in Diabetes |
| ACEi | Angiotensin Converting Enzyme Inhibitior |
| ADA | American Diabetes Association |
| ADVANCE | Action in Diabetes and Vascular Disease |
| AGI | Alpha Glucosidase Inhibitors |
| ARB | Angiontensin-II-Receptor Blockers |
| BMI | Body Mass Index |
| BP | Blood Pressure |
| CDC | Centers for Disease Control and Prevention |
| CT | Control trial |
| CPG | Clinical Practice Guidelines |
| CV | Cardiovascular |
| CVD | Cardiovascular Disease |
| DBP | Diastolic Blood Pressure |
| DC | Diabetes Care |
| DCCT | Diabetes Control and Complications Trial |
| DHL | Diabetes, Hypertension and Hyperlipidaemia |
| DM | Diabetes Mellitus |
| DPP-4 | Dipeptidyl Peptidase-4 |
| DRP | Drug Related Problems |
| FBG | Fasting Blood Glucose |

| | |
|---|---|
| FIP | Internation Pharmaceutical Federation |
| GLP-1 | Glucagon Like Peptide-1 |
| $HbA_{1C}$ | Glycated Haemoglobin |
| HDL | High Density Lipoprotein |
| IDF | International Diabetes Federation |
| INT | Intervention |
| LDL | Low Density Lipoprotein |
| MALMAS | Malaysian Medication Adherence Scale |
| MAP | Medication Assistance Program |
| MMAS-9 | Morisky Medication Adherence Scale |
| NHMS | National Health and Morbidity Survey |
| OAD | Oral Antidiabetes Agents |
| PC | Pharmaceutical Care |
| PCIs | Pharmaceutical Care Issues |
| PCNE | Pharmaceutical Care Network Europe |
| PCP | Pharmaceutical Care Program |
| PDM | Persatuan Diabetes Malaysia |
| QoL | Quality of Life |
| RCT | Randomized Controlled Trial |
| SMBG | Self-Monitoring Blood Glucose |
| SBP | Systolic Blood Pressure |
| SD | Standard Deviation |
| SU | Sulphonylurea |

| | |
|---|---|
| T1DM | Type 1 Diabetes Mellitus |
| T2DM | Type 2 Diabetes Mellitus |
| TC | Total Cholesterol |
| TG | Triglycerides |
| TZD | Thiazolidinediones |
| UC | Usual Care |
| UK | United Kingdom |
| UKPDS | United Kingdom Prospective Diabetes Study |
| UMMC | University Malaya Medical Centre |
| US | United States |
| WHO | World Health Organization |